

**Guideline to Implementation: A Rapid Clinical Care Pathway to
Care for Patients Affected by Chronic Constipation**

Date of IRB Approval: December 10, 2025

NCT06352827

PROTOCOL TITLE:

Guideline to Implementation: A Rapid Clinical Care Pathway to Care for Patients
Affected by Chronic Constipation

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1.0 Study Summary

Study Title	Guideline to Implementation: A Rapid Clinical Care Pathway to Care for Patients Affected by Chronic Constipation
Study Design	Pragmatic clinical trial
Primary Objective	The primary objective is to evaluate guideline adherence in medical decision-making, decision quality, and clinical outcomes among patients seen for chronic constipation in gastroenterology clinics.
Research Intervention(s)	During observational phase: no intervention During implementation phase: RED (FDA-cleared in vitro diagnostic device to evaluate constipation at bedside) MiChart OPA (Our Practice Advisory) – A decision support tool in MiChart to support care navigation using RED. For the remainder of this document, this will be referred to as MiChart OPA.
Study Population	Michigan Medicine gastroenterology patients with chronic constipation
Sample Size	218 patients
Study Duration for individual participants	Approximately one year
Study Specific Abbreviations/ Definitions	RED: Rectal Expulsion Device

2.0 Objectives

The primary objective is to evaluate guideline adherence in medical decision-making, decision quality, and clinical outcomes among patients seen for chronic constipation in gastroenterology clinics.

3.0 Background

Constipation is a very common gastrointestinal condition. While many patients improve with laxative treatments, up to half of constipated patients are not satisfied with their treatment. In up to one-third to one-half of these patients who fail laxatives, constipation can occur due to an inability to coordinate the series of events necessary to normally pass stool from the rectum. These patients do better with pelvic floor physical therapy to retrain the anal sphincter and pelvic floor muscles. Ultimately, little is known about how often providers and patients choose various diagnostic and treatment choices for this common condition.

4.0 Study Endpoints

The primary endpoint is fidelity to pelvic floor evaluation/management. We will define this as the percentage of encounters in which anorectal physiology testing and/or pelvic floor physical therapy is ordered or performed at the baseline routine-care gastroenterology office appointment.

Exploratory implementation endpoints will be acceptability, appropriateness, and feasibility from a provider perspective.

Exploratory effectiveness endpoints will be:

- Change in low-value diagnostic test utilization as a percentage of initial encounters in which a colonoscopy (for a patient that is not due for colon cancer screening or colon polyp surveillance per USPSTF guidelines or without documented procedural indication of rectal bleeding or weight loss) is ordered at the baseline routine-care gastroenterology office appointment or within the following 12 months
- Change in cross-sectional imaging (CT abdomen or CT abdomen/pelvis or MRI abdomen or MRI abdomen/pelvis in the absence of rectal bleeding, abdominal pain, vomiting or weight loss or personal/family history of inflammatory bowel disease) is ordered at the baseline routine-care gastroenterology office appointment or within the following 12 months
- Prevalence of receiving at least one patient-initiated contact to the nursing/provider team that required provided response (measured as whether or not the patient contacted the office by patient portal or phone call and received a provider response) within the first 30 days after the baseline routine-care gastroenterology office appointment.

- Prevalence of receiving at least one patient-initiated contact to the nursing/provider team that required provided response (measured as whether or not the patient contacted the office by patient portal or phone call and received a provider response) following the first 30 days after the baseline routine-care gastroenterology office appointment.
- Frequency of emergency department visits for constipation after the baseline routine-care gastroenterology office appointment during the one-year study period.
- Frequency of primary care visits for constipation after the baseline routine-care gastroenterology office appointment during the one-year study period.
- Frequency of virtual or in-office gastroenterology follow-up visits for constipation after the baseline routine-care gastroenterology office appointment during the one-year study period.

5.0 Study Intervention

There are TWO phases to this study. Each phase has a separate consent form.

OBSERVATIONAL PHASE (no device/intervention): We will measure usual care during this phase without any study intervention. Patients in the observational phase will not receive a study intervention. These patients will receive a baseline survey as described in Section 6.0 to assess clinical symptoms and healthcare utilization. Then, the research coordinator evaluates stated outcomes in the medical record without direct participant involvement.

IMPLEMENTATION PHASE: During this phase, the FDA-cleared RED and an investigational MiChart OPA and a supporting document called the RED brochure will be available in the clinic exam room as detailed in Section 5.0.1. The intervention components will **only** be available to patients that participate in this study during their baseline routine-care gastroenterology office appointment with their gastroenterology provider after consent is obtained and will not be available on further clinical visits. The provider will have a choice to use RED or not based on their own discretion, and therefore we hope to learn when providers might want or not want to use RED and also why. The use of RED, the RED brochure and the MiChart OPA will be designed specifically to not add additional time to the visit.

Optional additional supporting documents—the RED patient information page, and RED digital brochure—may be used to enhance patient understanding of the RED device before or after their scheduled appointments. These documents may be shared during the consent process, and the patient information page will also be available through MiChart for optional distribution in the after-visit summary, if consistent with clinic workflow. This process will be communicated during the

introductory in-person education session (see Section 6.0) to onboard provider co-investigators prior to the implementation phase.

The **RED brochure** and **RED digital brochure** are distinct resources. The RED brochure is a physical handout provided to patients in the clinic exam room, while the RED digital brochure is an electronic version that includes similar content to the patient information page but incorporates images. Together with the patient information page, these supporting documents were developed in collaboration with healthcare professionals and subject matter experts to explain the RED procedure and help patients understand their results.

Each participant will complete the baseline survey instrument as described in section 6.0 to assess clinical symptoms and healthcare utilization. Then, the research coordinator evaluates stated outcomes in the medical record without direct participant involvement.

5.0.1 Explanation of the FDA-cleared RED Device and its intended use

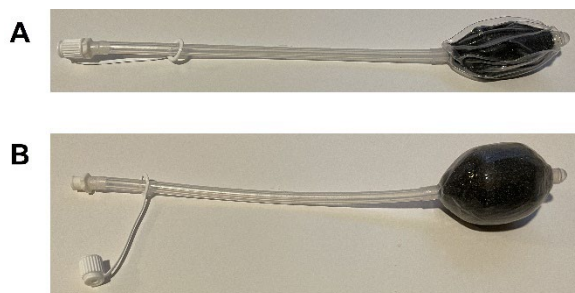


FIGURE: RED is inserted in a compressed state (A) and then inflated in the rectum by removing a cap on the end of the device (B).

The protocol to use RED is exactly the same as our longstanding clinical balloon expulsion testing protocol and FDA labeling. We developed the Rectal Expulsion Device (RED) as a simple, point-of-care, single use diagnostic test that can be performed during a routine clinic visit by a gastroenterologist. RED is intended to match the diagnostic performance and use of predicate technology while solving the practical challenges that inhibit widespread use of rectal sensation and balloon expulsion testing in clinical practice. After a complete physical exam at bedside including a digital rectal exam, the patient is turned on their side and RED is gently inserted into the rectum. The patient is asked whether they feel the urgent need to poop to evaluate rectal sensation. The patient is then given two minutes to expel RED while remaining in the lateral decubitus position similar to the position for a rectal exam in the office. During attempted expulsion, the subject is left to attempt defecation with the operator leaving the examination room and standing just outside of a closed door; this protocol is consistent with our standard routine clinical practice for anorectal function testing recognizing that many people are unable to defecate when an individual is watching them. The operator returns to the room after 2 minutes of attempted defecation consistent with usual standards of clinical care at centers offering these tests. The risk of remaining in the room is that the test results can be falsely abnormal and

negatively impact clinical decision-making. If the device is not expelled, the device can be safely removed at bedside. Based on our experience with 124 patients in which we demonstrated that physicians and non-physicians (technicians and nurses) were both comfortable using RED, our provider co-investigator partners will be fully trained to insert and remove the device. The operation of the device is technically similar to the balloon expulsion test, of which non-physician staff perform hundreds of procedures per year in routine standard-of-care at Michigan Medicine. As per usual protocols in performing motility testing at Michigan Medicine in clinical care, the PI will be available for oversight if any safety concerns arise.

5.0.2 Explanation of the MiChart OPA coupled with use of the RED device in the office during the implementation phase of this trial

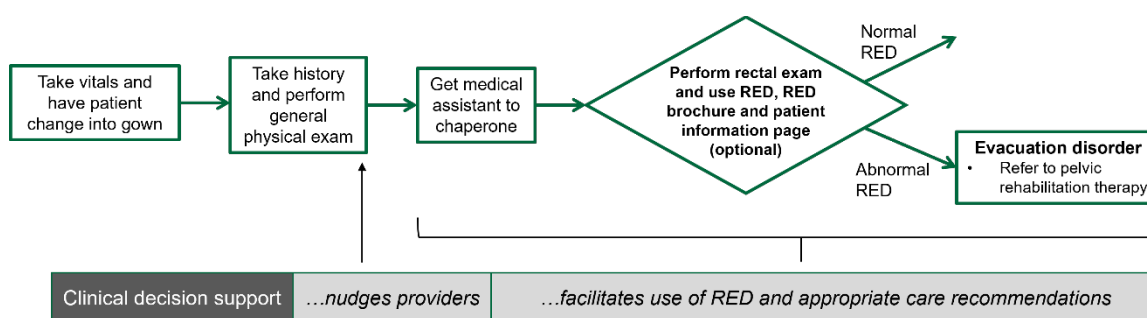


FIGURE: Example care pathway with the MiChart OPA and RED.

The MiChart OPA will pop-up during a clinical office encounter with a patient research participant that consents to this study for a provider that is participating in the study as a co-investigator. This alert will be activated by the study team member for participating patients. All recommendations by the MiChart OPA adhere to clinical practice guidelines that otherwise are not always followed in usual care (10.1053/j.gastro.2012.10.029).

6.0 Procedures Involved

Prior to beginning the implementation phase, we will hold an **in-person educational session** and develop materials that we will distribute to gastroenterology clinic providers (co-investigators) on the MiChart OPA pop-up decision support tool that might appear during an office visit and on the use of and training on RED.

The study team member will contact the patient to discuss the study and then offer electronic consent prior to the patient's routine care office consultation. If the patient consents, a baseline survey will be sent to the patient and must be completed prior to their routine care consultation.

Availability of RED and the MiChart OPA during the office visit during the implementation phase only: If the patient provides consent to the study, the MiChart OPA will deploy to the gastroenterology provider (co-investigators) on MiChart during the patient's next scheduled outpatient encounter with that provider (and not as the same day as consent), and RED and its brochure will be made available in the clinic room. The MiChart OPA, RED and its brochure will only be available during a single scheduled outpatient encounter and not on subsequent encounters. **Optional additional supporting documents**—the RED patient information page, and RED digital brochure—may be used to enhance patient understanding of the RED device before or after their scheduled appointments. These documents may be shared during the consent process, and the patient information page will also be available through MiChart for optional distribution in the after-visit summary, if consistent with clinic workflow. The use of RED and the MiChart OPA by gastroenterology providers (co-investigators) are described in Section 5.0. All care rendered for patients will be part of usual clinical care and billed to insurance. There are no study visits as part of this trial. The RED device will not be billed as it is for research purposes only.

Surveys during both the observational and implementation phases:

Clinical assessment surveys: Patients that participate will complete a survey on REDCap within two weeks prior to check-in for their baseline gastroenterology office consultation appointment that is part of routine care. This survey will contain the PAC-SYM and PAC-QOL questionnaires. This survey will be managed by the study team member. Patient demographics (age, sex/gender, race/ethnicity, partner status, employment status, health insurance plan, rurality), medical comorbidities, and medications will be recorded from the patient's medical record by the study team member and verified with the patient where there are missing data.

Healthcare utilization surveys: Patients that participate will complete a survey on REDCap within two weeks prior to check-in for their baseline gastroenterology office consultation appointment that is part of routine care.

Frequency of contact for the survey: If a patient still has not completed the survey before their routine care office consultation, REDCap will generate up to 5 email reminders and a study team member will contact the patient by phone to verify their correct email address and remind them to complete the survey up to three times.

For the implementation phase, participating provider co-investigators at the GI Clinics will be surveyed biannually (every 6 months) from the start of implementation up until the final RED is used. The survey will be a fillable PDF form and will contain the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention

Measure (FIM) instruments. The number of surveys completed may vary based on the length of time it takes to recruit patients during the implementation period.

7.0 Data and Specimen Banking

NA

8.0 Sharing of Results with Subjects

Study results will be published in the scientific literature upon completion of the study and incorporated into educational and clinical care materials to accompany a clinical care pathway for chronic constipation in clinical care.

9.0 Study Timelines

We anticipate a study duration of approximately one year per participant, including all follow-up.

10.0 Subject Population

For the observational phase, we will recruit patients at least 18 years of age that are scheduled to see a gastroenterology provider at the U-M Gastroenterology Clinics for chronic constipation as the primary complaint and that are able to participate in the physical therapy.

We will exclude individuals that have taken narcotic pain medication within the last 30 days, or that have been scheduled for or undergone anorectal manometry testing or seen a pelvic floor physical therapist to treat constipation and those that are pregnant. Pregnancy status is self-reported, no testing is required for this study.

Study eligible?	Inclusion criteria
	Is chronic constipation your main symptom?
	Are you able to participate in pelvic floor physical therapy?
Study Eligible?	Exclusion criteria
	Have you taken narcotic pain medication in the past 30 days?
	Have you ever had or been scheduled for a test called anorectal manometry in the past?
	Have you seen or been scheduled to see a pelvic floor physical therapist in the past?
	Are you pregnant?

For the implementation phase, we will recruit patients at least 18 years of age that are scheduled to see a gastroenterology provider at the U-M Gastroenterology Clinics for chronic constipation as the primary complaint.

We will exclude individuals that have taken narcotic pain medication (within the last 30 days) or that have been scheduled for or undergone anorectal manometry testing (in the last 12 months) or seen a pelvic floor physical therapist to treat constipation (in the last 12 months) and those that are pregnant. Pregnancy status is self-reported, no testing is required for this study.

Study eligible?	Inclusion criteria
	Is chronic constipation your main symptom?
Study Eligible?	Exclusion criteria
	Have you taken narcotic pain medication in the past 30 days?
	Have you ever had or been scheduled for a test called anorectal manometry in the last 12 months
	Have you seen or been scheduled to see a pelvic floor physical therapist in the last 12 months?
	Are you pregnant?

11.0 Vulnerable Populations

None

12.0 Local Number of Subjects

218 patients in two phases:

Observational Phase

Implementation Phase of RED and the MiChart OPA

13.0 Recruitment Methods

We will screen upcoming scheduled MiChart appointment for patients already scheduled for evaluation of constipation, in addition to patients referred for constipation to University of Michigan gastroenterology providers. Payment will not be made to subjects. As the patient is already a patient of U-M gastroenterology or upon receipt of a referral by the department, the study team member will contact the patient by phone up to 3 times about interest to participate in the study. Whether or not a patient participates in this study, patients receive routine care regardless of study participation as there are no study visits.

Optional additional supporting documents during recruitment—the RED patient information page, and RED digital brochure—may be used to enhance patient understanding of the RED device before their scheduled appointments. These documents may be shared during the consent process.

14.0 Withdrawal of Subjects

If a study participant fails to complete the baseline survey they will be withdrawn from the study.

If a participant voluntarily withdraws or is withdrawn by a study member from the research study, any collected data may be used in the study as indicated on the informed consent document. These data are not identifiable, and therefore cannot be reasonably removed.

15.0 Risks to Subjects

The novel balloon expulsion device, RED, has been constructed with similar characteristics as the commercially available device. Therefore, the rare risk of damage to the subject's anorectal tissue in the case that the novel device does not function as intended is small in comparison with the benefit of the development of this device that could eventually provide point-of-service information about a patient's anorectal function (see Section 5.0.1 on safety data for RED in 124 patients). This information will streamline the care of millions of patients suffering with rectal evacuation disorders.

Privacy/legal harm: Rare - Release of research data could lead to embarrassment or discomfort of the subject. To minimize this risk, all subject data will be kept in a locked file cabinet in the GI physiology laboratory and/or securely on the Michigan Medicine research drive.

Psychosocial harm: Rare - Procedure could be embarrassing or upsetting to subject. To minimize this risk all subjects will be thoroughly debriefed before the procedure and required to sign informed consent.

Potential Health/Physical Harm: Rare - The novel device, RED, has been constructed with smooth layers minimizing edges damaging a subject's tissue.

16.0 Potential Benefits to Subjects

Subjects will not directly benefit from this study.

17.0 Data Management and Confidentiality

Power analysis: To detect a 20% absolute increase in fidelity to pelvic floor evaluation/management, assuming a two-tailed 5% significance level with 80% power, and 15% pre- or post-visit survey non-completion rate—the minimum sample size is 109 patients per group (218 patients in total across our two periods: observational and implementation). This is within the context of >200 patients with chronic constipation referred monthly to U-M Gastroenterology per month. A 20% increase is consistent with low/conservative estimates of the percentage of patients who receive pelvic floor evaluation/management at baseline.

Dataset management: The **master data file** will contain a list of patients' MRN, demographics, current medications, co-morbidities listed on the problem list or past medical/surgical history. This information will be

populated by the study team member and/or PI based on chart review in MiChart with a list of MRNs for participating patients. For REDCap, each patient will be assigned a unique ID (1, 2, 3, etc) which will be notated in the master data file. This unique ID will be copied to REDCap along with patients' email address verified by the study team member at the baseline survey for the initial routine-care gastroenterology office consultation, to create a patient profile that will accurately capture their survey data as primary record. While the PI and/or study team member will create the patient ID in REDCap, the PI will not directly send the survey to patients in REDCap to minimize the risk of responder bias; as above, the baseline survey will be emailed to survey participants by the study team member via REDCap. The full **Statistical Analysis dataset** will be created by adding the patients' survey data from REDCap to the master data file and then stripped of MRN and email address thereby to not contain any personally identifiable information. The PI will be blinded to the results of the study until formal data analysis is complete. The PI will then be given access to a copy of the master data file to write manuscripts, and this copy version of the master data file will remain on the HIPAA-compliant research drive.

Data retention: Identifiable data will be retained for a period of seven years maximum, or earlier after manuscript publication and until FDA clearance is obtained.

18.0 Provisions to Protect the Privacy Interests of Subjects

All files will be password-protected and stored on the Michigan Medicine research drive with access limited to IRB-approved study personnel. The study team member will maintain these datasets to ensure patient contact for study completion. At the end of the study period after the manuscript is accepted and FDA approval is obtained, the MRN will be erased. REDCap survey software will contain an email address for each patient so that it is able to send surveys to participating patients. Access to REDCap will be limited to the PI and study team member. Physical copies of files related to RED will be kept in a locked file cabinet.

19.0 Compensation for Research-Related Injury

NA

20.0 Economic Burden to Subjects

There are no study visits, and all visits are part of routine clinical care. Thus there is no added economic burden for patients to participate in this study.

21.0 Consent Process

The study will be discussed and the consent form will be provided to the patient by the study team member. Electronic consent will be obtained by

the study team member following at least a one day waiting period. The consent forms for Observational Phase and Implementation Phase are uploaded separately. In accordance with the Conflict of Interest management plan, Dr. Shah (PI) will not obtain consent.

Optional additional supporting documents—the RED patient information page, and RED digital brochure—may be used to enhance patient understanding of the RED device before their scheduled appointments. These documents may be shared during the consent process.

22.0 Process to Document Consent in Writing

We will follow Michigan Medicine’s SOP: Electronic Documentation of Consent.

23.0 Setting

Michigan Medicine gastroenterology clinics

24.0 Resources Available

Michigan Medicine GI has considerable experience in conducting clinical research and sees sufficient volume to ensure successful recruitment (over 1,000 referrals for chronic constipation annually). Dr Shah is funded for 75% of his time to ensure completion of this study.